



# SEBRA<sup>®</sup>

operation manual

VT-108723-IE

MINI™ Model 2380  
Hand-Held Tube Sealer  
Power Source



VANTE INC  
IGNITING INNOVATION



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## Consumer information

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### Disclaimer

This manual is intended as a guide to provide the operator with necessary instructions on the proper use and maintenance of certain Vante products. This manual should be used in conjunction with instruction and training supplied by qualified Vante personnel.

Any failure to follow the instructions as described could result in impaired product function, injury to the operator or others, or void applicable product warranties. Vante accepts no responsibility for liability resulting from improper use or maintenance of its products.

Utilization of Vante products may require the operator to handle and dispose of blood-contaminated material. An operator must fully understand and implement all regulations governing the safe handling of blood products and waste, including the policies and procedures of their facility.

Handling and use of any blood products collected using Vante equipment are subject to the decisions of the attending physician or other qualified medical personnel. Vante makes no warranty with respect to such blood products.



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# Chapter 1

## Preliminary information

### Document scope

This manual is a guide for the operation, care, and maintenance of the Vante® SEBRA® Model 2380 MINI™ Hand-Held Tube Sealer Power Source.

### Intended audience

This manual is intended for use by personnel having technical skills and a thorough understanding of the products, procedures, and safety requirements for the collecting, processing and handling of blood and/or blood products.

### Symbols found in this document

The terms Note, Caution and Warning are used in this manual with the following symbols to notify the operator of important and/or critical information.



*Note: provides useful information regarding a procedure or operating technique when using Vante material.*



**Caution:** advises the operator against initiating an action or creating a situation that could result in damage to equipment, or impair the quality of the blood products; personal injury is unlikely.



**Warning:** advises the operator against initiating an action or creating a situation that could result in serious personal injury to the donor, the operator, or the blood product recipient.



## Symbols found on the device

The following symbols may be found on the device or device packaging.



**Shock hazard**



**Attention**

Consult accompanying documents.



**Protective earth (ground)**

Identifies any terminal intended for connection to an external conductor, for protection against electrical shock in case of a fault.



**Power ON**



**Power OFF**



**Fuse**



**Electrical and electronic equipment waste (applies to EU only)**

Dispose of the device using a separate collection method (according to EU and local regulation for waste electrical and electronic equipment).



**Serial number**



**Catalog number**



**Manufacturer**



**Authorized representative in the European Community**

## Device specifications

### Physical specifications

The approximate dimensions and weight of the Model 2380 device are as follows:

Table 1-1, Physical Specifications

	Length/cm (in.)	Height/cm (in.)	Width/cm (in.)
Sealing head	20.3 cm (8.0 in)	2.5 cm (1.0 in)	3.8 cm (1.5 in)
Power source	33.8 cm (13.3 in)	4.1 cm (1.6 in)	12.2 cm (4.8 in)
Weight of sealing head	0.3 kg (0.6 lbs)		
Weight of power source, carrying pouch, strap, and battery pack	2.1 kg (4.7 lbs)		

The following environmental conditions should be respected pertaining to operation and storage of the Model 2380 device:

### Environmental conditions

Table 1-2, Environmental Conditions

Condition	Value
Ambient operating temperature	4 °C to 38 °C (39.2 °F to 100.4 °F)
Storage/transportation temperature	-12 °C to 50 °C (10 °F to 122 °F)
Operating humidity level	Maximum relative humidity 70%
Pollution degree	2



**Warning: Equipment not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.**

### Electrical specifications

The electrical specifications for operating the Model 2380 device are as follows:

Parameter	Specification
Power source	12 V NiCad battery pack.
Battery charger Input: Output:	100-240VAC, 50-60 Hz 15VDC, 55mA and 1.4A
RF power output	40 watts minimum into matched 50Ω load, at initial power up
Primary frequency	40.68±0.02 MHz

# Chapter 2

## Product overview

The Vante® SEBRA® Model 2380 MINI™ Hand-Held Tube Sealer Power Source (Sealer) is a compact, portable, battery powered device that employs SMART™ electronics (which detect the end of the seal and arcing problems) to generate radio frequency (RF) to make uniform, quality seals on a variety of tubing sizes without power adjustment by the user. The Sealer comes with a hand-held, manually activated sealing head (the Model 1105) which creates a seal that is formed by the sealing head jaws in such a way as to take segment separation easy and uniform. The Model 2380 is approved for sealing the blood collection tubing while the blood collection needle remains in the donor's arm.

### Application

The Model 2380 Power Source is an instrument that generates RF power for making seals on tubing made of RF reactive thermoplastic materials typically used in blood banks, blood processing facilities and transfusion centers. Tubing utilized in the collection and handling of blood and blood products is typically made from thermoplastic vinyl, namely polyvinylchloride, or PVC, and it is this application for which this product is specifically intended.

### Theory of Operation

The physical properties of PVC plastic tubing (and other RF-reactive thermoplastic materials) cause it to dielectrically heat at a molecular level in the presence of RF energy. This energy causes the plastic to soften due to the friction of the vibrating molecules. In this softened condition, the plastic becomes weldable because the molecules are free to intermingle under the application of external forces, such as compression. If allowed to cool while the forces are applied, the material will be permanently reshaped.

The Power Source is an instrument that generates, when actuated, a controlled amount of RF energy at the sealing head while mechanically compressing the tubing across its diameter during the dielectric sealing and forming process. When the energy is removed and the tubing is allowed to cool under compression, a permanent seal is produced.



*Note: Since the Power Source generates RF, other instruments or equipment in its proximity may be affected by radio frequency interference (RFI) unless their electronic circuitry is properly shielded for RFI.*

The Power Source generates RF power, the frequency of which is controlled by a solid state oscillator/amplifier operating at 40.68 MHz. The RF energy level and seal time are controlled by means of a proprietary solid state circuit design, allowing various tubing sizes to be automatically accommodated. Additionally, a built-in arc detect mode will normally preclude sealing if the tubing exterior, ground jaw and/or RF jaw surfaces are affected by contamination and/or moisture. *Thus, the Model 2380 Tube Sealer requires no manual power or timing adjustment by the user.*

The Power Source will automatically detect a battery low condition, notifying the operator of impending seal deterioration via visual and audible indications. This detection circuit is activated when the battery voltage has dropped to a point in which a limited number of good seals remain.

## Component identification

1. Model 2380 RF power source
2. Operation manual
3. Model 2380200 battery pack
4. Model 1103 RF power cable (Optional Model 1109 coiled cable not pictured)
5. Carrying strap
6. Battery charger
7. Power cord
8. Carrying pouch

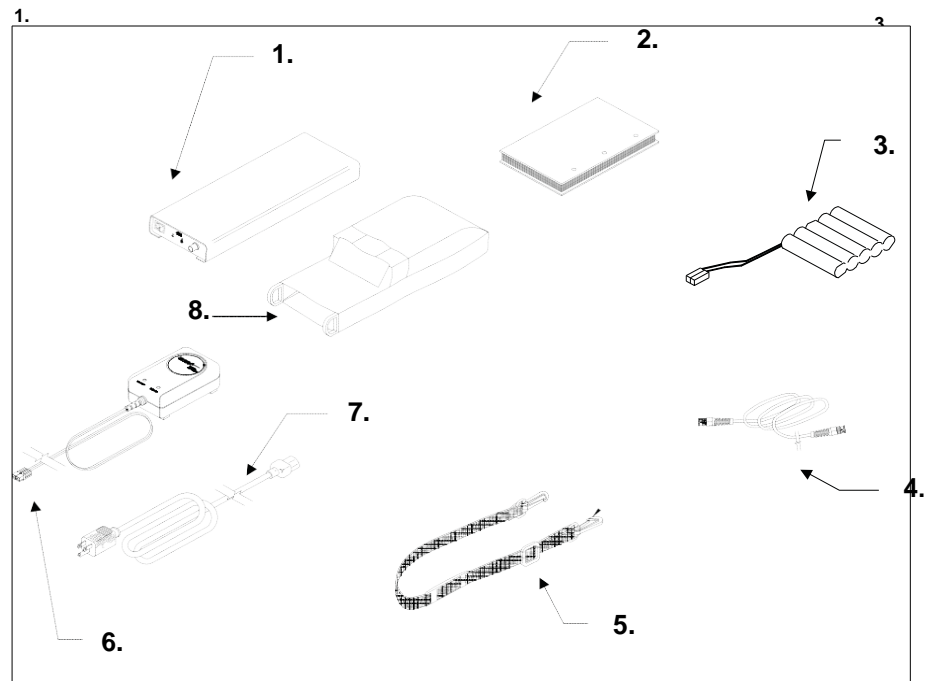


Figure 2-1, 2380 MINI™ Hand-Held Tube Sealer Components

Shown in 2-2, is the power interface panel on the front of the RF power source. The serial plate (2-3), located on the underside of the RF power source, indicates the model number and serial number of the unit.

Refer to the serial number when contacting Vante® Customer Care Center. See Table 2-1, “2380 Sealer Component Functions,” on page 2-3 for a complete description of the functions of the indicated items.

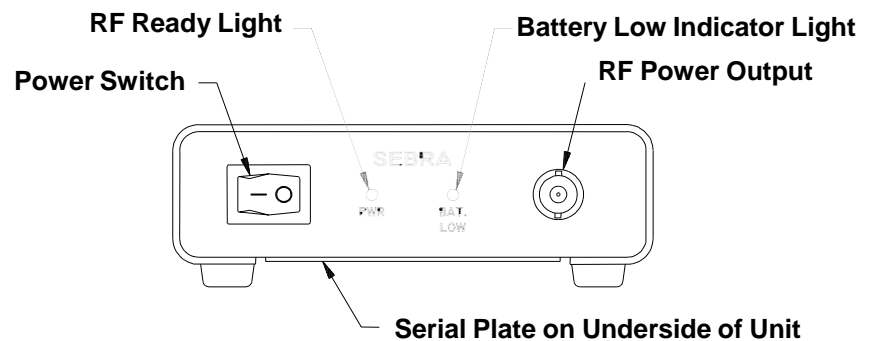


Figure 2-2, Model 2380 Power Interface Panel

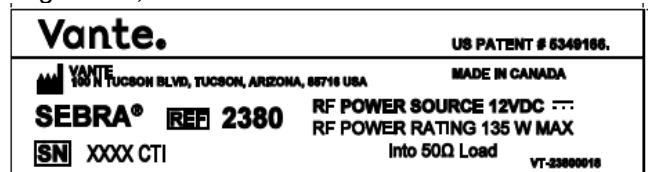


Figure 2-3, Serial Plate for Model 2380

## Component Functions

**Table 2-1, 2380 Sealer Component Functions**

<b>Component</b>	<b>Function</b>
Model 2380 RF Power Source	Provides RF power to the sealing head. Automatically controls sealing time.
Carrying Pouch and Strap	Provides finish protection to and easy transport of RF power source. Also provides storage for the sealing head and RF power cable.
RF Ready Light	Green LED located on the unit's power interface panel, labeled "PWR". Illuminates when RF power is ready.
Model 1105 Sealing Head	Hand-held, manually activated unit consisting of the RF jaw/tube assembly, ground jaw and lever. Seals tubing by compressing it between the RF and ground jaws while applying RF energy. Jaws must remain closed for one second after indicator light turns off.
Model 23802000 Battery Pack	Rechargeable 12V NiCad battery which provides power to the RF power source.
Model 1103 or Model 1109 RF Power Cable	Connects the sealing head to the RF power source, at the RF power output connector located on the front of the unit.
Model 2389 Battery Charger	Provides external battery charging capability. <b>CANNOT BE USED AS AN AC ADAPTER FOR THE RF POWER SOURCE.</b>
Power Switch	Turns battery power "on" or "off". Rocker type switch located on the power interface panel of the RF power source next to the RF ready light.
RF Power Output	Female BNC connector providing RF power to the Model 1105 sealing head through the RF power cable. Located on the power interface panel.
Battery Low Light	Amber LED located on the front of the RF power source. Illuminates when the battery requires recharging. An audible signal is also sounded to alert the user of the low battery condition.
Serial Plate	Indicates the model number, the serial number, and the required power input of the RF power source. Located on the underside of the unit.

## Operating environment

The Power Source will perform effectively when used in a typical blood bank, blood processing facility or transfusion center environment. Variations in actual environmental conditions of the facility and/or the level of contamination and/or moisture on the ground and RF jaws and/or tubing exterior may affect actual performance. Users are advised that when temperature and humidity conditions seem less than what might be considered comfortable for humans, it is best to slow the rate of repetitive sealing, to be certain the sealing head and tubing are clean and dry, and to frequently check the quality of seal being produced.

To ensure optimal performance, it is recommended that the sealer be acclimated to the ambient environmental operating temperature for approximately one hour prior to use.

## PVC tubing size Categories

Shown in Table 2-2 are typical recommended size categories and corresponding dimension ranges of PVC tubing which can be sealed with the Power Source.



*Note: Sealing modes (see "Sealing modes" on page 2-4) are defined for each category of tubing size. Be sure the category of tubing size being sealed is determined and the sealing mode guidelines are checked before using the Sealer (Table 2-2).*

**Table 2-2, PVC Tubing Size Categories**

Tubing Size Category	Outside Diameter Range	Wall Thickness Range	Examples
Small	0.080-0.147 inch 2.0-3.7 mm	0.020-0.030 inch 0.5-0.8 mm	Anti-coagulant and saline drip lines
Medium	0.148-0.179 inch 3.8-4.5 mm	0.020-0.035 inch 0.5-.89 mm	Blood bag tubing
Large	0.180-0.250 inch 4.6-6.4 mm	0.030-0.04 inch 0.8-1.02 mm	Apheresis and dialysis sets

## Sealing modes

"Intermittent" mode refers to a sealing process in which no more than 5 seals are produced rapidly (as quickly as the Sealer can normally produce for the tubing size being used) within a minimum 1 minute time period. For example, if it takes 10 seconds to produce 5 seals, then the Sealer must sit idle for at least 50 seconds. This sealing mode may be used for tubing of ALL sizes.

"Continuous" mode refers to a sealing process in which seals are made at regularly spaced time intervals for an extended period. This mode may be used for tubing of MEDIUM (typically, blood bag tubing) size only.



*Note: To perform continuous sealing on tubing of SMALL and LARGE sizes, a different sealer may be required. Contact Vante for more information.*

"Maximum" mode, which may be used for tubing of MEDIUM and LARGE sizes only, refers to sealing in which a prescribed maximum number of seals is made at a rapid, repetitive rate, followed by a specified period of no Sealer activity.



*Note: To perform maximum sealing on tubing of small size, a different sealer may be required. Contact Vante for more information.*

## Duty cycle

The Sealer "duty cycle" is defined as the time period, in seconds, between consecutive, repetitive seals. It is significant for continuous and maximum modes only; intermittent mode has no strict time interval between seals.



**Warning: Every sealing mode must always be performed in accordance with the sealing procedures described in Chapter 3 of this manual.**

Table 2-3 lists *suggested* duty cycles to help users estimate their maximum allowed sealing rate(s).

**Table 2-3, Suggested Duty Cycles**

Sealing Head	Sealing Mode	PVC Tubing Size	Duty Cycle	Defined As
Model 1105	Intermittent	All	As required	No more than 5 seals within a 1 minute time period
	Continuous	Small	--	Not recommended
		Medium	3 seconds	Seal rate equivalent of 1200 seals per hour
		Large	--	Not recommended
	Maximum	Small	--	Not recommended
		Medium	2 seconds	Maximum 50 seals in 1 minute 40 seconds, then none for 4 minutes
		Large	6 seconds	Maximum 10 seals in 1 minute, then none for 10 minutes

## Seal spacing



*Note: The Sealer is designed to allow repetitive seals to be made on a length of tubing filled with blood or blood products. However, several factors control how closely the seals may be spaced. For standard blood bag tubing, follow the instructions provided by the bag manufacturer.*

## General guidelines

Seals that progress along an open-ended length of tubing may be spaced as desired, but ½ inch (1 cm) is the recommended minimum.

Seals that progress along a close-ended length of tubing, as in a segmenting process, must be spaced approximately one inch (2.5 cm) to avoid rupture of the tubing due to pressure build-up.



**Warning: Never attempt to make segmentation seals closer than recommended without validating for seal integrity.**

## Chapter 3

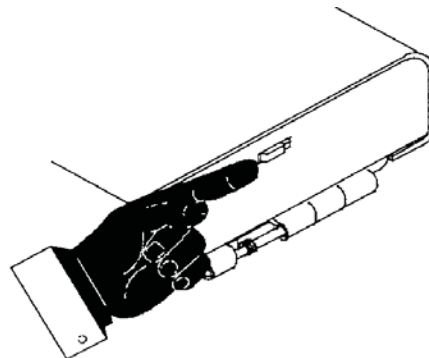
### Setup and sealing procedure

1. Remove the components from their protective shipping containers and visually inspect them for obvious damage. Contact Vante® Customer Care Center if any damage is found.



*Note: If possible, retain shipping containers and packing materials for future use.*

2. For optimal performance, batteries should be fully charged prior to use.
3. Check to see that the power switch is in the off position. Open the battery compartment door on the power source case by sliding the latch to the right. See Figure 3-1, Opening Battery Compartment Door.



*Figure 3-1, Opening Battery Compartment Door*

4. Position the battery connector as shown in Figure 3-2, Battery Connector Location.



**Caution:** Use only with battery packs equipped with a Positive Thermal Cutout (PTC) device and approved for use with Vante® SEBRA® Model 2380 MINI™.



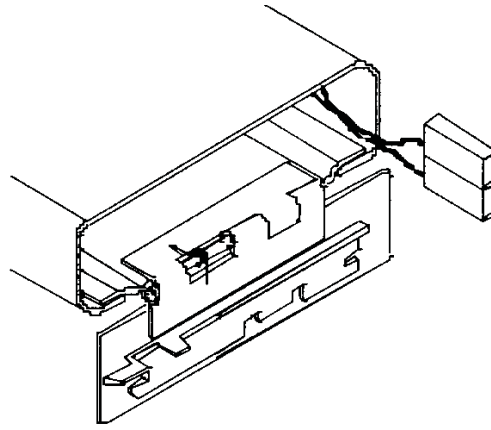


Figure 3-2, Battery Connector Location

5. Ensure the connectors are positioned on the side (not the top or bottom) of the battery. Slide the battery into the battery compartment by holding the battery underneath and ensuring the wires are aligned properly (See Figure 3-3, Properly Installing the Battery, below).



*Note: Ensure the latch is underneath the device and position hand underneath the battery while inserting in the case. This prevents any damage to the wires or battery. Do not pull on the wires.*

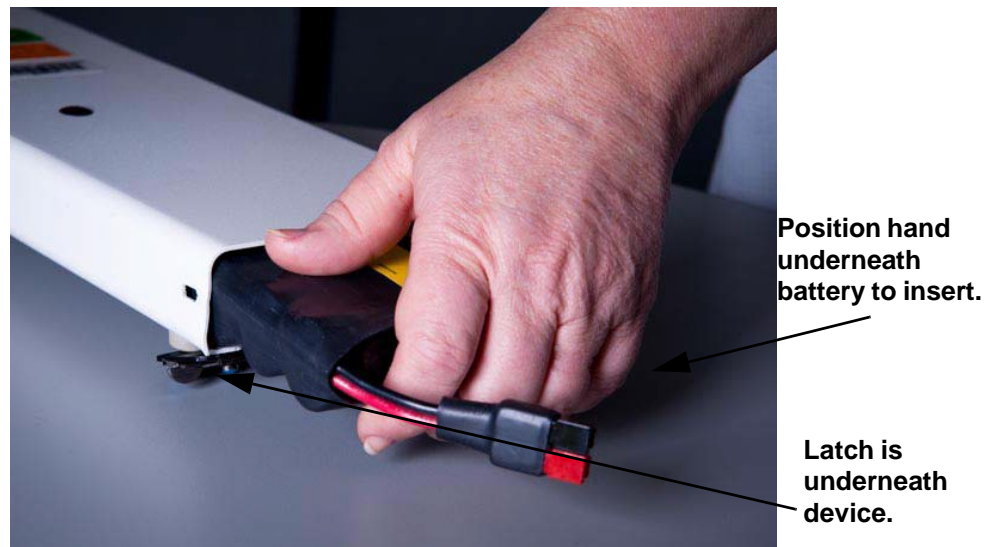


Figure 3-3, Properly Installing the Battery

6. Once the battery is fully seated, engage the RF power source connector to the battery connector. See Figure 3-4, Battery to Power Source Connection.



**Caution:** The battery pack and RF power source connectors are keyed to engage properly. Be sure that the RED battery pack connector is engaged into the RED power source connector, and the BLACK into the BLACK. If they do not engage easily, do not attempt to force the connectors together. Improper battery connection will result in damage to the RF power source and will void the warranty.

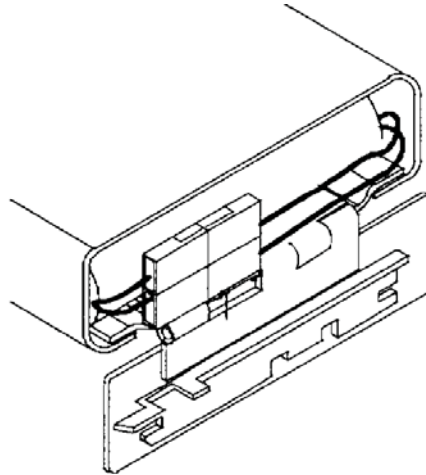


Figure 3-4, Battery to Power Source Connection

7. Close and latch the battery compartment door. If desired, install the RF power source into its carrying pouch.



**Caution:** Do not use the battery outside the sealer case or operate the sealer without a door. Damage to the sealer and battery may occur.

8. Attach one end of the RF power cable to the power source and the other end to the sealing head. Connect the cable by pushing the connectors together and rotating clockwise until locked (see Figure 3-5, Attachment of RF Power Cable).

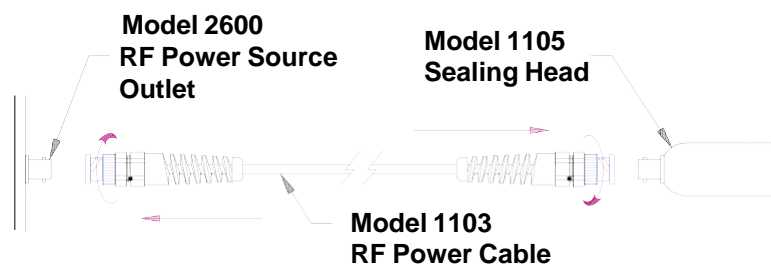


Figure 3-5, Attachment of RF Power Cable



**Warning:** Do NOT attempt to use any other length or type of RF power cable. Unauthorized substitution of the RF power cable may result in malfunction of the Power Source and will void the warranty!

9. Turn on the unit by pushing the rocker-type power switch on the power panel to the "I" (on) position.

The RF ready light on the power panel will illuminate, which indicates that the Sealer is ready for use.


10. See the Operation Manual for the Sealing Head for information on handling and sealing with the device.




**Warning: Never use the Power Source in the presence of flammable anesthetics. A potential explosion hazard may exist if arcing should occur in the presence of such compounds.**


# Chapter 4

## Battery replacement


 **Note:** The Power Source is powered by an easily removable and rechargeable 12V NiCad battery pack. The battery pack will provide approximately 1500 seals on typical blood bag tubing when fully charged and sealing system is properly tuned.

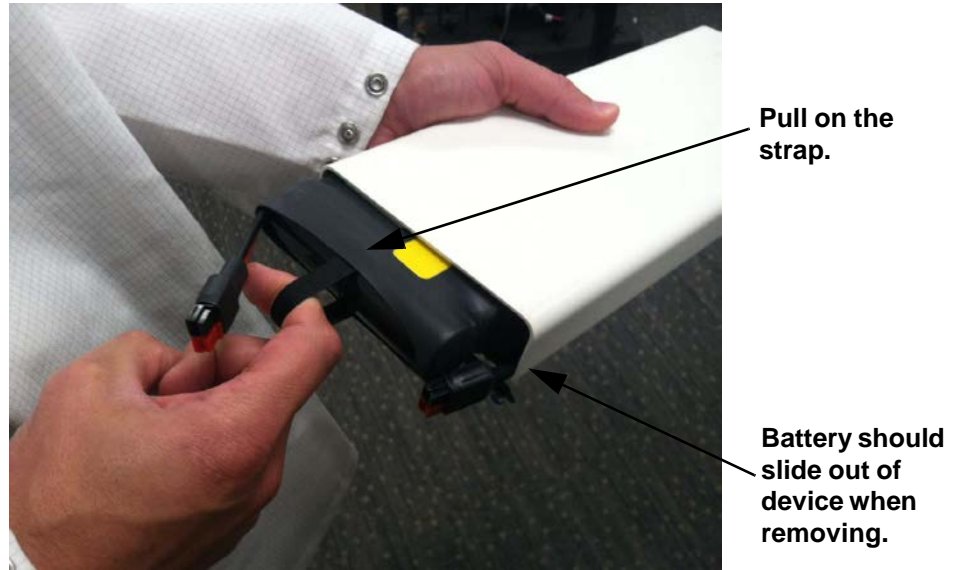
 **Caution:** Use only with battery packs equipped with a Positive Thermal Cutout (PTC) device and approved for use with Vante® SEBRA® Model 2380.

The battery low condition is signaled when an audio alarm sounds and the battery low indicator light is illuminated. When this occurs, recharge battery (see “Battery charging” on page 4-3) or replace the battery pack with a freshly charged back up battery pack.

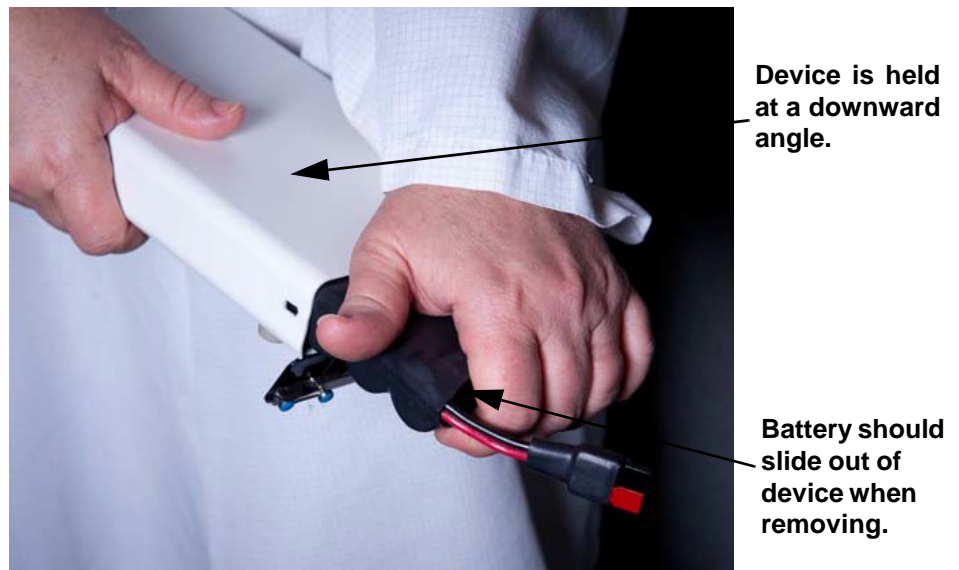
 **Note:** Arcing at the sealing head may cause a battery low condition to be indicated, even when the battery is not low. In such a case, shut the power source off and be sure the sealing head and/or tubing are dry and clean (to eliminate the possibility of further arcing). Turn the power source on and continue sealing. If the battery low condition is indicated again and arcing has not occurred, then it is time to exchange the battery pack with a fully charged battery pack.

1. Prior to battery pack removal, turn the power switch to the off position. Disconnect the sealing head and RF power cable and remove the power source from the carrying pouch, if necessary.
2. Open the battery compartment door by sliding the latch to the right. Disconnect the battery connector from the power source connector and slide the battery pack out of the compartment by pulling on the strap.

 **Note:** Remove the battery pack by using the strap or by holding the device at a downward angle and sliding the battery out of the device casing. Remove by pulling the battery down and out. This angle allows the battery to slide out more easily, avoiding damage to the battery and wires. Do not pull on the wires. (See Figure 4-1 and Figure 4-2.)



*Figure 4-1, Properly Removing the Battery Using the Strap*



*Figure 4-2, Properly Removing the Battery by Sliding*

3. Install a fully charged battery pack as described in Chapter 3.

## Battery charging



**Caution:** DO NOT attempt to charge non-chargeable batteries. Damage to equipment could occur.



**Caution:** The battery charger should never be used as an AC adapter by plugging the RF power source connector into the battery charger connector. The Power Source will not function properly and the charger may be damaged.

4. Plug the battery charger into an AC power source (wall outlet) and verify that the green power "ON" indicator light is illuminated.



**Note:** Check to see that the power cord plug matches the power receptacle for the country in which the battery charger is being used. If it does not, or if the green power "ON" indicator light does not illuminate, contact Vante Customer Care Center.

5. Once the battery pack is removed from the RF power source (see "Battery replacement" on page 4-2), plug its red and black connector into the matching connector on the battery charger.



**Caution:** The battery pack and charger connectors are keyed to properly engage. Be sure that the RED battery pack connector is engaged into the RED battery charger connector, and the BLACK into the BLACK. If they do not easily engage, do not attempt to force the connectors together. Improper battery connection will result in damage to the battery pack and/or charger and will void any warranties.



**Caution:** Charge the battery pack only with the Vante® SEBRA® Model 2389 Rapid Charger to ensure safety and prevent battery damage.



**Note:** If amber charge status light fails to illuminate after connection, check to see that the battery pack is properly connected to the charger. If green power "ON" indicator light flashes, leave battery pack on charger for one hour. If amber charge status light still fails to illuminate after one hour, disconnect battery pack from charger and contact V Customer Care Center for battery pack replacement.

6. Leave battery pack on battery charger until completely charged. Battery pack is completely charged when amber charge status indicator light flashes every 1/8-second.

Charge status is represented by the amber charge status indicator light as Table 4-1, "Charge Indicator Light Status".

**Table 4-1, Charge Indicator Light Status**

Charge Status	Charge Indicator Light Activity	Description
Battery Absent	Amber light not illuminated	Battery pack not connected.
Pending Mode	Amber light flashes every 1½ second	Charger in a slow charging mode. Maintain battery pack on charger. Charger will automatically switch to Fast Charge when appropriate.
Fast Charge	Amber light continuously illuminated	Charger in fast charge mode.
Float Charge	Amber light flashes every 1/8 second	Fast charging complete, battery pack ready for use.



**Caution:** If Fast Charge period (amber charge status light is continuously illuminated) exceeds 6 hours, disconnect battery pack from battery charger and contact Vante Customer Care Center.



**Caution:** If Pending Mode period (amber charge status light flashes every 1½ second) exceeds one hour, disconnect battery pack from charger and contact Vante Customer Care Center for battery pack replacement.

5. Disconnect the battery pack from the charger and reinstall into the RF power source (see Chapter 3) or set aside as a back up. Disconnect battery charger from AC power source (wall outlet).



**Note:** It is important to remove battery pack from the charger before disconnecting the charger from the AC power source (wall outlet), or battery pack will lose its charge.

Battery packs not in active use should be maintained by discharging and recharging every 30 days

# Chapter 5

## Cleaning and maintenance



**Warning:** Because the Model 2380 is capable of detecting RF arcing (which may be due to moisture or other contaminants in the sealing region), the Sealer performance will be reduced if the sealing region becomes contaminated or wet with fluids. (Note that arcing at the sealing head may cause a battery low condition to be indicated, even when the battery is not low.) To obtain satisfactory seals at all times, be sure the sealing region and all adjacent areas are always kept clean and dry.



*Note:* It is recommended that topical cleaning of the sealing head (see the Operation Manual for the Sealing Head) be performed when blood or moisture contaminate the immediate vicinity of only the sealing region, i.e., the area where seals are produced between the ceramic RF jaw and the ground jaw.

General cleaning of the sealing head (see the Operation Manual for the Sealing Head) should be performed periodically or when blood or moisture contaminates the area outside the immediate vicinity of the sealing region.

### Cleaning the power source case

1. Ensure that the power switch located on the power interface panel on the RF power source is in the off position. Disconnect the RF power cable from the power source.
2. Apply a cleaning solution made from a mild detergent or household cleaner such as Formula 409® (NO BLEACH) and water to a soft cloth. Wipe the power source case with the damp cloth until clean. Make sure the power source is completely dry before putting back into service.



**Warning:** Do not apply fluids directly to the power source case and do not over saturate the cleaning solution applicator. The fluids may run into the electronic components and cause contamination of the electronics and subsequent unit malfunction. Never immerse the power source in any liquid.

### Troubleshooting and maintenance

#### Troubleshooting activities

The following table provides simple maintenance activities that may resolve device issues. If the problem continues to occur, contact the local Vante representative.

**Table 5-1, Troubleshooting guide**

<b>Problem</b>	<b>Cause</b>	<b>Action</b>
No RF power out.	Cables not properly connected.	Be sure all connections are correct (refer to Chapter 3).



**Table 5-1, Troubleshooting guide**

	Power switch not on.	Be sure the power switch is in the on position.
	Sealing Head magnet dislodged.	See the Operation Manual for the Sealing Head.
	Battery is dead.	Replace battery.
	Power Source Malfunction.	Call Vante
	Hand-Held Sealing Head malfunction.	See Operation Manual for Hand-Held Sealing Head.
	RF cable malfunction.	Replace cable.
Arcing is a problem.	Tubing is wet or contaminated.	Ensure the outside of the tubing, the sealing region and adjacent areas are clean and dry.
	Sealing Head operation error.	See Operation Manual for the Sealing Head.
Poor seal quality is occurring.	Sealing Head/Power Source combination may not give optimum performance.	Check to see if another Sealing Head connected to the power source gives better results.
	Improper tubing used.	Be sure tubing for blood and blood products (usually PVC) is being used. Some other tubing may give poor seals, or none at all.
Amber indicator light on battery charger fails to illuminate.	Battery pack improperly connected to charger.	Be sure that the battery pack is properly connected to the charger.
	Battery is dead.	Replace battery.
	Battery charger improperly connected to AC power source.	Be sure the battery charger is connected to the proper AC power source.



*Note: Arcing at the sealing head may cause a battery low condition to be indicated, even when the battery is not low.*

### Failure isolation

If the Sealer fails to operate properly, connect a different sealing head and RF power cable to the power source to isolate the failed component.

If the Sealer performs properly, then the questionable sealing head is probably defective. If the Sealer fails to function properly, then the power source may be defective. In any event, contact the local Vante representative.

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## Customer service

### Services

#### Clinical training

The local Vante representative will provide staff training upon delivery of the equipment and should be contacted to organize further instruction if needed.

#### Repair service

Vante maintains a worldwide network of company-trained service representatives responsible for responding to technical needs concerning equipment. If service beyond the routine maintenance and cleaning described in this manual is required, the local Vante representative should be contacted to provide specific instruction.

#### Product return guidelines

If, for any reason, merchandise must be returned to the company, the customer should contact the local Vante representative to arrange for repairs or returns using procedures to ensure proper handling and subsequent analysis. No returns will be accepted without advanced authorization.



**Warning: Vante products must be properly cleaned and packaged prior to their return. It remains an important responsibility of the customer to reduce potential health hazards by being aware of the risks involved in the shipping, handling and testing of this material. Units returned to Vante for repair are subject to biohazard charges if any component is contaminated with blood or blood products.**

# Chapter 6

## General information

Vante manufactures a variety of instruments that incorporate the use of radio frequency (RF) for sealing, welding, or forming thermoplastics. Typical uses include the sealing of blood bag and apheresis tubing, and plastic welding or forming manufacturing processes. When in operation, these RF instruments emit radio frequency energy to people, other instruments, and equipment located in close proximity. Current Vante RF instruments operate at a frequency authorized by the Federal Communications Commission (FCC) and the International Telecommunications Union (ITU) for industrial, scientific, and medical (ISM) use. The following is an advisory regarding RF instrument use and associated safety considerations.

### RF effects on human tissue

Vante RF instruments are in compliance with (IEEE) C95.1-1991, standards for safe exposure levels to RF energy. However, misuse or direct contact between tissue and RF electrode(s) can result in severe RF burns.

### RF effects on pacemakers

There is no evidence that Vante RF instruments interfere with the function of modern cardiac pacemakers.

### Electrical safety

Vante RF devices meet or exceed appropriate electrical safety standards, and pose no electrical shock hazard when used with properly fused and grounded outlets.

### RF effects on electronic equipment

Vante instruments produce RF power, and during operation emit some RF energy from the electrodes. While most modern electronic equipment and instruments provide shielding from RF energy, improperly shielded electronic devices operating in close proximity to an RF instrument may be affected. If interference is suspected, appropriate electronic shielding, moving equipment further away from the RF instrument, or operating from a different electrical circuit may be necessary.

## **RF effects in potentially explosive atmospheres**

Do not operate Vante RF instruments in any area with a potentially explosive atmosphere. It is possible for the RF electrodes to arc, initiating an explosion or fire.



**Warning: Vante recommends strict adherence to the procedures specified in the instrument Operation Manual. Misuse or modification of an instrument may result in unsafe or hazardous situations.**

# Chapter 7

## Appendix A: EMC standard requirements



**Caution:** The Model 2380 device must be operated in an environment in accordance with the guidance given in IEC 61326 Standard, *Electrical equipment for measurement, control and laboratory use – EMC requirements*.

### Operation precautions

Mobile radio frequency (RF) communication equipment not approved by Vante and portable communication equipment can affect the system. Any accessories and cables not approved by Vante used in conjunction with the device may increase hazards and influence compatibility with EMC requirements. Therefore, non-approved accessories and cables must not be used.

In addition, the Model 2380 device and accessories must not be placed directly adjacent to, or on top of other equipment, unless specifically approved by Vante.

### Electromagnetic immunity



*Note: The Model 2380 device is intended for use in the electromagnetic environment specified below. The customer or operator of the Model 2380 device should ensure that it is used in such an environment.*

Emissions test	Compliance	Electromagnetic environment guidance
RF emissions CISPR 11	Group 2	The Model 2380 system must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
RF emissions CISPR 11	Class A	The Model 2380 system is suitable for use in all establishments, other than domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

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